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5/27/97

Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, California 94502-7070
Telephone: (510) 337-6700

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Our Reference: 29-53395

May 8, 1997

Martin Vantil
2685 South Madera Avenue
Kerman, California 93630-9119

WARNING LETTER

Dear Mr. Vantil:

Tissue residue reports from the United States Department of Agriculture (USDA) and an investigation of your dairy on April 9 and 10, 1997, by Food and Drug Administration (FDA) Investigator Thomas W. Gordon have revealed serious violations of the Federal Food, Drug, and Cosmetic Act as follows:

A food is adulterated under Section 402(a)(2)(D) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512. On January 27, 1997, you sold a cow (identified by USDA laboratory report number 382712) to be slaughtered for human food. This cow was delivered for introduction into interstate commerce by your firm, and was adulterated by the presence of illegal antibiotic drug residues. USDA analysis of tissues from this cow revealed tetracycline in the kidney at 19 parts per million (ppm), in the liver at 11 ppm, and in the muscle at 3.5 ppm. A tolerance level for tetracycline in the edible tissues of lactating dairy cows has not been established.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions which are so inadequate that medicated animals bearing possibly harmful drug residues are likely to enter the food supply. For example, our investigator noted the following:

1. You lack an adequate system for determining the medication status of animals you offer for slaughter.

2. You lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs.

3. You lack an adequate system for assuring animals have been treated only with drugs which have been approved for use in their class of animal or species.

4. You lack an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling.

5. You lack an adequate system for determining that quantities of drugs are being accounted for to prevent the possible overdosing of animals.

The drug Maxim 200 brand oxytetracycline HCL that your establishment uses on lactating dairy cows is adulterated under Section 501(a)(5) of the Act in that it is a new animal drug within the meaning of Section 201(v) and is unsafe within the meaning of Section 512(a)(1)(B) of the Act since it is not being used in conformance with approved labeling. Labeling for Maxim 200 specifically states it is for use only in non-lactating dairy cattle. Your practice of using oxytetracycline to treat lactating cows is likely the cause of the illegal residues found in the animal you consigned for slaughter.

Your use of the drug Hanford's brand penicillin G procaine is not in conformance with its approved labeling. Product labeling states the it is to be administered intramuscularly in cows. Your practice of treating cows with 8 mLs of penicillin G procaine intramammary is likely to result in harmful residue levels in the cows you sell for slaughter.

Your use of the drug Nolvasan Cap-Tabs brand chlorhexidine is not in conformance with approved labeling directions when you use it to treat your lactating dairy cows for the removal of the retained placenta. Nolvasan Cap-Tabs brand chlorhexidine is not approved for use in cattle.

Failure to comply with the label instructions on the drugs you use to treat your cows presents the likely possibility that illegal residues will occur and makes the drugs unsafe for use.

We request that you take prompt action to ensure that animals which you offer for sale as human food will not be adulterated with drugs or contain illegal residues.

Introducing adulterated foods into interstate commerce is a violation of Section 301(a) of the Act.

Causing the adulteration of drugs after receipt in interstate commerce is a violation of Section 301(k) of the Act.

You should be aware that it is not necessary for you to have personally shipped an adulterated dairy cow in interstate commerce to be responsible for a violation of the Act. The fact that you offered an adulterated dairy cow for sale to a slaughter facility where it was held for sale in interstate commerce is sufficient to make you responsible for violations of the Act.

This is not intended to be an all-inclusive list of violations. It is your responsibility to ensure that all requirements of the Act are being met. Failure to achieve prompt corrections may result in enforcement action without further notice, including seizure and/or injunction.

Within fifteen days of the receipt of this letter, notify this office in writing of the specific steps you have taken to correct these violations and preclude their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which corrections will be completed. Your response should address each discrepancy brought to your attention during the inspection and in this letter, and should include copies of any documentation demonstrating that corrections have been made. Please direct your reply to Thomas W. Gordon, CSO, Post Office Box 169, Fresno, California, 93707.

Sincerely yours,

Robert B. Johnson for

Patricia C. Ziobro
District Director
San Francisco District

cc: [redacted]